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(54) Electric generator, compress, combination of compresses, and system for the treatment of wounds by means of electric stimulation.

(57) A wound treatment system comprises an electrically conductive wound compress (2), a return electrode (3), an electric generator (7) and cables (4) for forming electric connections between said components. According to the invention the wound compress comprises a laminate with a first layer (17) of electrically conductive material capable of forming an essentially uninterrupted surface contact with the wound surface and a second layer (16) of electrically conductive electrode material, said second layer exhibiting a conductivity in directions parallel to the planes of the layers which is higher than the corresponding value of the first layer, said second layer (16) being adapted for attachment of an electric connection, and said generator (7) being adapted to optionally emit a direct current signal or a pulsed signal comprising pulses with a pulse duration around 0,1 ms or a combination of the above signals.

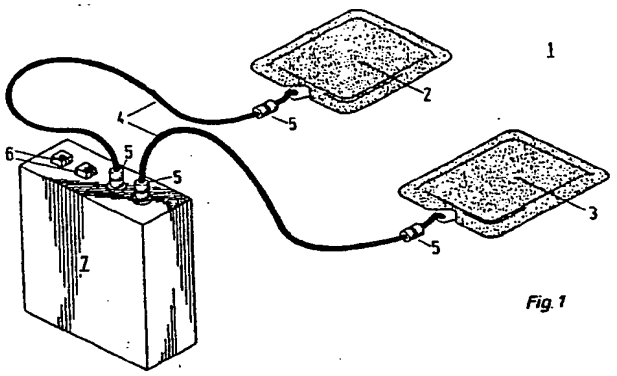

Fig.1

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lieved to have substantial disadvantages. The application of the electrodes must be laborious and bears the risk of causing pain. The e lectrode is believed to be sensitive to liquid which may occur by oozing wounds, involving the danger of loosening the electrode or changing the conductivity properties of the electrode. Changes in the conductivity properties may lead to undesirable changes of the stimulation signal, and in the case of more localized variations, there may be the risk that the current applied will be concentrated over more limited areas with the danger of developing hot spots, skin irritation or of shunting the current around the area where it should have been applied. In case the skin or the wound exhibits a non-planar surface, there may be risks of gaps where the gaze does not conform to the skin and where no current is applied. Another risk is that of a drying-out of the gaze, whereby the conductivity may drop unacceptably. A further disadvantage is the use of a reusable electrode involving risks of contamination and infection.

US patent no. 4 706 680 discloses an adhesive skin electrode developed for TENS (mentioned above), for recording electro cardiograms or for the application of electric defibrillation signals. This electrode comprises a viscous hydrophilic gel, which is described in details in the co-assigned US patent no. 4 684 558. The gel is used as contact element to the skin and a reusable electrode may be placed in contact with the distal side of the gel relative to the skin. This gel is manufactured from an aqueous solution of linear water-soluable polyethylene oxide by crosslinking the polyethylene oxide through radiation so as to develop a cohesive viscous gel. The gel can be made electrically conductive by the admixing before radiation of a dissolved electrolyte, e.g. a salt. A variety of conductivity values may be obtained by a suitable selection of a salt concentration.

SUMMARY OF THE INVENTION

Brief description

The present invention provides a wound treatment system comprising an electrically conductive wound compress, a return electrode, an electric generator and means, e.g. cables, for electrically interconnecting the above parts, which system is characterized in that the wound compress comprises a laminate with a first layer of electrically conductive material capable of forming an uninterrupted surface contact with the surface of a wound or with a skin surface, and a second layer of electrically conductive electrode material, said second layer exhibiting an electric conductivity in directions parallel to the planes of the layers which is higher than that of the first layer, said second layer being adapted for attachment of an electric connection, and in that the generator is adapted to emit either a direct current signal or a pulsed signal comprising pulses with a pulse width below 1 ms, in particular below 0,5 ms and preferably about 0,1 ms, or to emit a combination of the above signals.

The DC current application is believed to produce wound healing, and the pulse signals, when applied directly into the wounds and not applied to a hand or to another distal place as known in the prior art, e.g. by TENS treatments, have been discovered to produce a very good pain-relief effect.

Thus a system is provided for wound treatment, which system is so simple and safe to use that it may be possible to let a patient administer the system himself, possibly in his home. The system provides effective pain relief and healing of the wounds. The treatment does not involve any risk of skin irritation. There is a choice between various functions so that the system may be used exclusively for pain relief, exclusively for healing or for a combination of these, depending upon the particular electric signal emitted by the generator.

The material for forming the surface contact with the wound surface or with a skin surface may be any skin-compatible electrically conductive material capable of conforming to the surface so as to produce an essentially uninterrupted surface contact.

According to one particular embodiment this material may comprise electrically conductive foam plastic.

According to a more preferred embodiment the electrically conductive material comprises a hydrophilic electrically conductive gel capable of absorbing liquid by swelling. The viscous and liquid absorbent properties ensure an excellent and endurable surface contact even by various kinds of oozing wounds. These compresses may be left on the skin for relatively extended time intervals, e.g. several days, which means that the system needs only limited attention, is cheap in use and does not cause any substantial discomfort for a patient.

A particularly advantageous gel is the gel disclosed in the above-mentioned US patents nos. 4 684 558 and 4 706 680. This gel is very sticky, but may still be peeled off the skin when removal is desired without any discomfort and without leaving any residue. This gel is wa ter absorbent up to three times its own weight and with no substantial deterioration of its adhesive properties or conductivity properties. The gel has a substantial heat

This leakage current may, however, be kept below a suitably moderate level provided that the electric conductivity of the skin contact layer is suitably low and the distance between the two electrode regions is suitably high. The inventor has discovered that with this compress, wherein the wound electrode and the return electrode are arranged close to each other, sufficient electric stimulation of the tissue below the skin where the compress is applied may be induced to produce the above-mentioned advantageous effects. This embodiment is obviously simpler to manufacture, to stock and to market as well as to use as only one piece of compress needs to be handled instead of two, as required in other embodiments.

According to a preferred embodiment the generator is adapted to emit a signal comprising a train of pulses with a frequency of repetition about 100 Hz over a period of time ranging from 40 ms to 400 ms, and preferably around 250 ms, followed by a pulse intermission whereafter the sequence is repeated corresponding to a frequency of pulse train repetition about 2 Hz. Practical testing has proved that this signal provides a particularly good stimulation of the blood flow in the body extremities.

According to a preferred embodiment the generator is programmed for automatically switching over after the expiry of a first predetermined interval of time from the emission of a continuous pulsed signal, possibly superimposed onto a direct current signal, to rhythmic pulse trains, possibly superimposed onto a direct current signal, and after the expiry of a second predetermined interval of time to emit a direct current signal alone. This provides a simpler operation and improves the certainty for the treatment as the generator automatically ensures that a pain relieving, a blood-flow stimulating and a healing signal is emit ted. Furthermore this improves the safety that undesirable side effects, e.g. induced headache, are not produced.

According to a further aspect the invention provides a method for pain-relieving and/or healing treatment of wounds for a patient by means of electric stimulation, wherein an electrically conductive wound compress is placed in contact with the wound and an electrically conductive return electrode compress is placed onto the skin at a distance from the wound, said method being characterized by the application onto the two electrically conductive compresses of an electric signal comprising a combination of a direct current signal and an alternating current signal, e.g. a pulse signal. In practicing this method any of the above-mentioned wound treatment systems, compresses and generators may be used.

Brief Description of the Drawings

Further features, advantages and objects of the invention will appear from the following detailed description of preferred embodiments given with reference to the accompanying drawings, wherein

figure 1 is an overall perspective view of a wound treatment system according to the invention,

figure 2 shows a wound treatment compress according to the invention in a planar view as seen from the skin contact side,

figure 3 shows a wound treatment compress in a sectional view, the section taken along the line 3-3 in figure 2,

figure 4 shows a wound treatment compress according to another embodiment in a sectional view similar to the view in figure 3,

figure 5 is a graphical plot showing the stimulation signal versus time in large scale,

figures 6a, 6b and 6c are graphical plots to a smaller scale than figure 5, figure 6a showing a periodic pulse signal, figure 6b showing a rhythmic pulse signal and figure 6c showing a direct current signal,

figure 7 is an overall perspective view of a wound treatment system according to another embodiment of the invention, and

figure 8 is a sectional view through a wound treatment compress according to the embodiment of figure 7.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Description of the Drawings

Reference is first made to figure 1 showing a wound treatment system generally indicated by the reference numeral 1, a wound compress or wound plaster 2, a return electrode compress or return electrode plaster 3, an electric generator 7, cables 4 to connect the respective compresses to the generator and cable connectors 5 so that the individual parts of the system may be connected or disconnected in a simple manner. The electric generator 7 is provided with operation buttons 6 so that the operation may be started, stopped and controlled.

As indicated in figure 2 the wound treatment plaster comprises an electrically conductive skin contact surface 11 essentially rectangular and with a projecting tab 18, to which a cable 12 has been

tive connectors. In a first mode of operation the generator emits periodic pulses as illustrated in the plot in figure 5. The width of the individual pulses is below 1 ms, in particular below 0,5 ms and preferably about 0,1 ms. The pulses are emitted periodically, the cyclus time from one pulse to the consecutive pulse being within the range of 2-100 ms, in particular between 5-20 ms and preferably about 10 ms corresponding to a pulse frequency of 100 Hz. The pulse amplitude is defined by an adjustable current value, which may be adjusted within the range of 0-60 mA, the selected current level being maintained essentially independently of the load, except that the output voltage is limited so as not to exceed a maximum of 150 V.

Whereas the generator in a first mode of operation emits periodic pulses, it may be switched to a second mode of operation to emit a train of pulses over a period of time ranging from 40-400 ms, in particular from 100-300 ms and preferably about 250 ms, followed by a pulse intermission and then repeating this sequence at a pulse train base frequency between 1-5 Hz, and preferably about 2 Hz. This mode of operation is designated rhythmic pulses. In a preferred embodiment, wherein the pulse repetition rate is 100 Hz over a period of 200 ms, 25 pulses will be emitted, and assuming a pulse train base frequency of 2 Hz the intermission will last 250 ms.

In a third mode of operation the generator emits a direct current signal as indicated in figure 6c, said signal being maintained at a predetermined level of current essentially independent of the load, e.g. at 800 μA, except that the output voltage is limited to not exceed 9 V. Assuming a wound plaster contact area of 83 cm^2, the current density over this area will be about 10 μA per cm^2.

The above-explained modes of operation may be combined as illustrated in figures 6a and 6b, e.g. to emit as illustrated in figure 6a periodic pulses superimposed onto the direct current signal, or the generator may emit the rhythmic signal illustrated in figure 6b comprising pulse trains with intermediate pauses and superimposed onto the direct current signal.

The effects of the various stimulation signals are believed to be so that the periodic signal primarily is pain relieving, that the rhythmic signal in particular improves the blood flow in the body extremities and that the direct current signal in particular enhances the wound healing.

According to a preferred embodiment the generator is preprogrammed so that it, upon being switched on, initially emits the signal of figure 6a over a first predetermined interval of time, e.g. 20-25 minutes, thereafter switching automatically to emit the signal shown in figure 6b, which is emitted over a second predetermined interval of time, e.g. 20-25 minutes, then switching automatically to emit the signal of figure 6c, said signal being emitted for a third predetermined interval of time, e.g. 60-120 minutes, whereafter the generator is automatically turned off. Practical experience has shown that this programme ensures a good pain-relieving effect, a good effect onto the blood flow and a good healing effect at a minimum consumption of electric power so that the batteries in the generator are preserved as much as possible. The generator may hereby be constructed comparatively small in order to be easily portable and the service life of the batteries is extended.

Reference is now made to figures 7 and 8 wherein another advantageous embodiment of the invention is shown. Some of the elements of this embodiment are similar to those of the embodiments described above and therefore referenced with the same reference numerals. Figure 7 shows a wound treatment system comprising a generator 9 and a double compress 20, these parts being interconnected by suitable cables 4 and connectors 5 similarly as the other embodiments.

As clearly illustrated in the sectional view of figure 8 the double compress correspondingly as the compress of figure 3 comprises a skin contact layer 17 and a backing layer 14. The embodiment of figures 7 and 8 differs by the electrically conductive electrode layer being divided into two regions, a wound electrode region 21 and a return electrode region 22, respectively. These two regions are separated by a demarcation region 23 with no electrically conductive electrode layer so that the distance between the closest parts of the two electrode regions is everywhere above a predetermined lower limit, e.g. 10 mm. As evident from figure 7 the wound electrode region 21 and the return electrode region 22 is each provided with a respective electrical connection tab 18 and they may be used as a wound electrode and a return electrode, respectively.

Since the skin contact layer 17 has some electric conductivity, some leakage current may obviously pass the skin contact layer 17 in the direction parallel to the front surface and across the demarcation region 23. However, this leakage current may be kept below an acceptable level provided that the conductivity of the skin contact layer 17 is suitably low and provided that the width of the demarcation region 23 is everywhere at least 10 mm. The inventor has discovered that the current stimulus signal by this double compress surprisingly penetrates sufficiently far into the tissues below the skin to induce the same advantageous effects as explained above.

With this embodiment a simpler handling and application of the compress is obtained as only one piece of compress needs to be applied. The manu-

periodically with a cycle frequency within the range of 20-500 Hz, in particular from 50-200 Hz and preferably about 100 Hz, and being adapted to emit the pulsed signal cyclically to form a pulse train over a range of time lasting from 40-400 ms, in particular from 100-300 ms and preferably about 250 ms, followed by an intermission whereafter this sequence is repeated, the repetition rate of pulse trains forming a base frequency between 1 and 5 Hz, and preferably about 2 Hz.

4. The generator of claim 3, **characterized** by being adapted to automatically switch over its mode of operation after a first predetermined interval of time from emitting a continuous pulse signal superimposed onto the direct current signal to emit periodic pulse trains superimposed onto the direct current signal and to switch over after a second predetermined interval of time to emit a direct current signal.

5. A compress for treatment of wounds by means of electric stimulation, **characterized** by comprising a laminate with a first layer of electrically conductive material capable of forming an essentially uninterrupted surface contact with a wound surface or with a skin surface and a second layer of electrically conductive electrode material, said second layer exhibiting a conductivity in directions parallel to the planes of the layers which is higher than the corresponding value for the first layer, said second layer being adapted for attachment of an electric connection.

6. A compress for the treatment of wounds by means of electric stimulation, **characterized** by comprising a laminate with a first layer of electrically conductive material capable of forming an essentially uninterrupted surface contact with a wound surface or with a skin surface and a second layer of electrically conductive electrode material, said second layer exhibiting a conductivity in directions parallel to the planes of the layers which is higher than the corresponding value for the first layer, said second layer being divided into at least two regions with no direct electric interconnection, each of the two regions being adapted for attachment of a respective electric connection.

7. The compress of claim 5 or 6, **characterized** by said first layer comprising an electrically conductive hydrophilic gel formed by cross-linking of linear polyethylene oxide dissolved in water.

8. The compress of any of the claims 5 through 7, **characterized** by said second layer comprising a carbon fiber fabric.

9. A combination of compresses for the treatment of wounds by means of electric stimulation comprising a wound compress intended for fitting over or adjacent the wound site and a return electrode compress intended for fitting distally from the wound site, **characterized** by said wound compress comprising a laminate with a first layer of electrically conductive material capable of forming an essentially uninterrupted surface contact with a wound surface or with a skin surface and a second layer of electrically conductive electrode material, said second layer exhibiting a conductivity in directions parallel to the planes of the layers which is higher than the corresponding value for the first layer, said second layer being adapted for attachment of an electric connection, and by the wound compress first layer exhibiting an electric conductivity in directions perpendicular to the surface which is lower than the corresponding value of the return electrode compress first layer.

10. The combination of compresses of claim 9, **characterized** by the return electrode compress first layer exhibiting a conductivity in directions perpendicular to the contact surface which is 1,5 to 2 times the conductivity of the wound compress first layer in directions perpendicular to the contact surface.

Fig.3

Fig.4

Fig.2

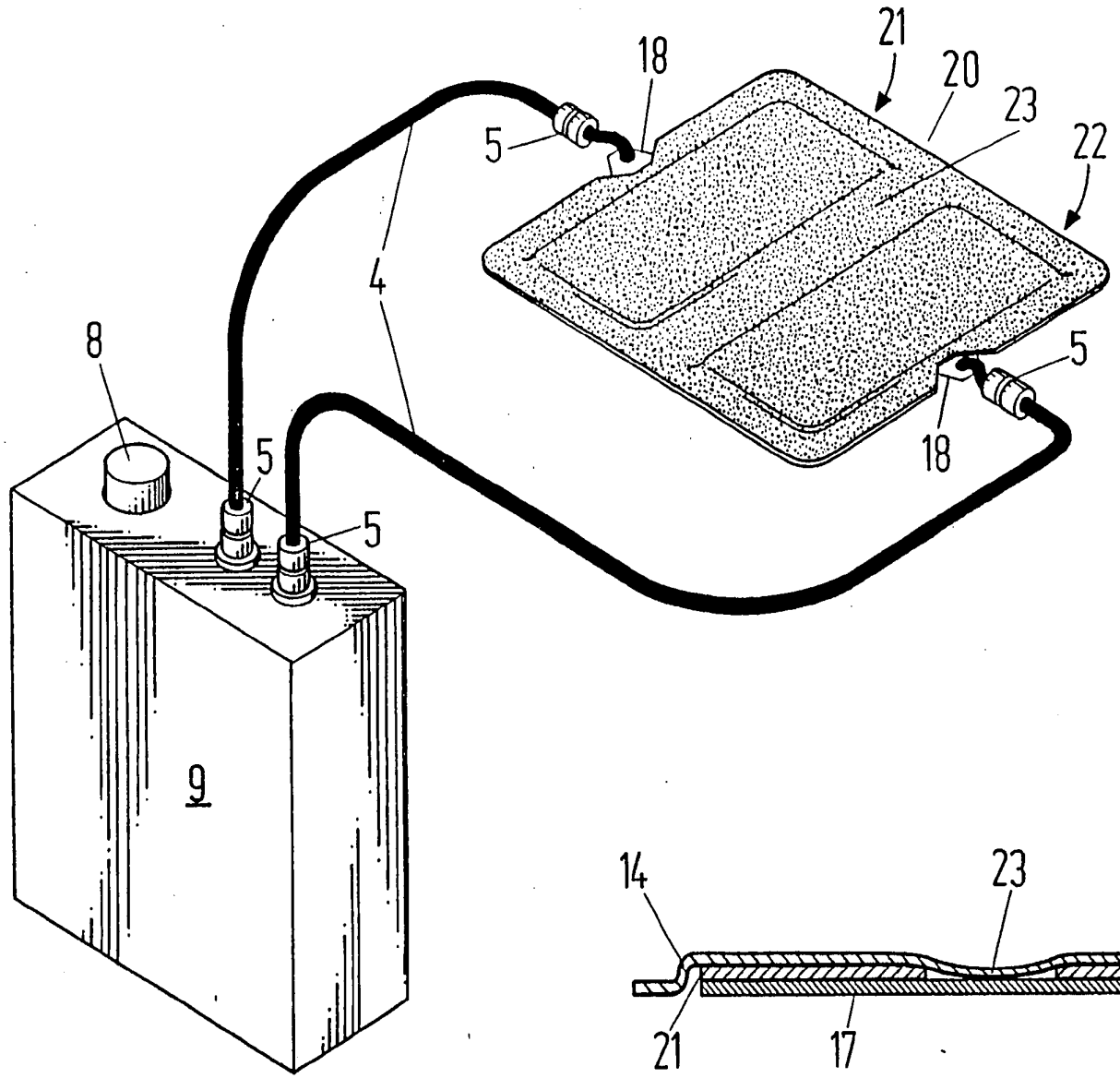

Fig.7

Fig.8

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